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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,171	01/25/2002	Thomas A. Vendola	PC11014AGLK	5278

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,171	VENDOLA, THOMAS A.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 1, 2004 has been entered.

Applicant's amendments filed July 1, 2004 have been entered.

Claims 1-38 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanes et al. (US Patent 5,855,913), reference of record.

Hanes et al. teaches porous particulate for drug delivery (See claim 1; col. 11, line 55 – col. 15, line 42: Example 2).

Claims 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Straub'698 (US Patent 5,853,698), reference of record.

Straub'698 teaches porous pharmaceutical particles for imaging (col. 7, line 9 – col. 9, line 34).

Claims 33-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Straub'300 (US Patent 6,395,300), reference of record.

Straub'300 teaches porous pharmaceutical particles for drug delivery (See the abstract). Straub'300 also teaches that such particles be made to become tablet (See particularly the abstract).

Response to arguments

Applicant's arguments filed July 1, 2004 averring the herein claimed composition is prepared from a different method and thus, possesses different properties than that of the cited prior arts have been considered, but are not found persuasive. Please note that the instant claims 33-37 are drawn to a composition claims. The different methods

of preparing the same do not distinguish the final compositions from one to the other. In other words, the method of preparation in claims that drawn to composition does not lend patentable weight unless the applicant can demonstrate the composition prepared by the instant method is structurally different than that prepared by the methods taught in the cited prior art. However, no such evidence is seen herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-32 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub'300 in view of Remington (Remington's Pharmaceutical Sciences, 18th ed., 1990, pages 1633-1647), references of record.

Straub'300 teaches a method of preparing porous pharmaceutical microparticles by mixing the drug with solvents and a pore forming agent to form emulsion, and then evaporate the solvent and the pore forming agent to form the microparticles (See the abstract; also col. col. 11, line 47 – col. 13, 46; claim 1). Straub'300 also teaches the particles of porous matrix can be formulated further into a tablet (See particularly col. 13, line 39). Straub'300 teaches that the pore forming agent as ammonium bicarbonate (See claim 7). Straub'300 also teaches the amount of the solid pore forming agent as 10 to 100% of that of the active drug (See col. 11, line 45).

Straub'300 does not teach the wet or dry granulation method being employed. Straub'300 does not expressly teach the compression of the tablet being employed. Straub'300 does not teach the employment of a compressive agent into the composition. Straub'300 does not teach the herein claimed amount for the solid violatilizable agent.

Remington teaches that wet and dry granulation method is a well-known, commonly used methods of preparation for tablets (See page 1641, col. 2 – page 1644, col. 2, last paragraph). Remington also teaches compressible sugars such as lactose, sucrose, and starch can be used for direct compression (See page 1645, col. 2, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ wet and dry granulation method and incorporate a compressive agent into the method of Straub'300. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet by further compressing the porous particles of Straub'300.

One of ordinary skill in the art would have been motivated to employ wet and dry granulation method and incorporate a compressive agent into the method of Straub'300 because the wet and dry granulation and incorporating compressive agents are well-known in the art to be useful for formulating a tablet. Employing well-known method and excipients in formulating pharmaceutical composition would be obvious as being within the purview of skilled artisan.

One of ordinary skill in the art would have been motivated to prepare a tablet by further compressing porous particles of Straub'300. Compression of particles into a tablet is a well-known method for tablet preparation. Straub'300 teaches that the porous particles therein are useful in further processing into tablets. Therefore, employing any well-known method and excipients in formulating pharmaceutical tablet such as compression and the compression aids would be obvious as being within the purview of skilled artisan. Furthermore, Tthe optimization of result effect parameters (amount of excipients employed) is obvious as being within the skill of the artisan.

Response to arguments

Applicant's arguments filed July 1, 2004 averring the instant application concerning the increase in porosity as a process related enhancement only to increase tablet strength by directing examiner's attention to examples 1-3 in the instant specifcation have been considered, but are not found persuasive. It is not clear if the examples are relevant to the cited prior arts or not. The cited prior arts, taken together, suggest the instant method of preparing a pharmaceutical composition. Hanes is not even cited as the basis for rejection under 35 USC 103.

Applicant's arguments filed July 1, 2004 averring the instant method not requiring the steps taught in Straub, i.e., dissolving the drugs particles, have been considered but are not found persuasive. Although the instant invention does not require the steps taught in Straub, it does not expressly exclude such steps.

Applicant's arguments filed July 1, 2004 averring the failure of Straub to be applicable in the instant method have been considered, but are not found persuasive.

Straub teaches a method of forming porous granules by adding the volatile substances to the actives and then removing the volatile substances and the solvent. The resulting porous granules can be further formulated into tablets through conventional methods, e.g., compression. The only steps not taught in Straub would be the wet or dry granulation steps. However, as taught in Remington, wet or dry granulation is well-known conventional method to formulate powders or granules in pharmaceutical art. Incorporating such conventional method into the method Straub would be considered obvious, absent showing the criticality of the granulation steps.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Patent Examiner
Art Unit 1617

SAN-MING HUI
PATENT EXAMINER